

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

Paper No. 21

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte CARSTEN B. RODSTEN

Appeal No. 2000-1747
Application No. 08/784,237

HEARD: July 11, 2001

Before OWENS, WALTZ and DELMENDO, *Administrative Patent Judges*.

WALTZ, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1 through 14, which are the only claims pending in this application.

Appeal No. 2000-1747
Application No. 08/784,237

According to appellant, the invention is directed to an improvement of a known process for coating medical devices with hydrophilic coatings which comprises applying to a substrate

Appeal No. 2000-1747
Application No. 08/784,237

surface which does not have a hydrophilic coating a solution of agents which will combine to form the hydrophilic coating along with an osmolality promoting agent (Brief, pages 2-3). Copies of illustrative claims 1 and 7, directed to the method and the device produced, are attached as an Appendix to this decision.

The examiner has relied upon the following references as support for the rejections on appeal:

Lambert	4,585,666	Apr. 29, 1986
Johansson et al. (Johansson)	4,906,237	Mar. 6, 1990
Whitbourne	5,001,009	Mar. 19, 1991

Claims 1-14 stand rejected under 35 U.S.C. § 112, first paragraph, for failing to fulfill the written description and enablement requirements (Answer, page 7).¹ Claims 1-3, 7-9, and 13-14 stand rejected under 35 U.S.C. § 102(b) as anticipated by Lambert or Whitbourne (Answer, page 8). Claims 1-14 stand rejected under 35 U.S.C. § 102(b) as anticipated by Johansson (Answer, page 10). We reverse all of the examiner's

¹These separate rejections have been combined as one rejection although based on the two requirements of the first paragraph of § 112, as noted, for ease of discussion.

Appeal No. 2000-1747
Application No. 08/784,237

rejections for the reasons set forth in the Brief, Reply
Brief, and the reasons which follow.

OPINION

A. The Rejections under 35 U.S.C. § 112, first paragraph

The examiner separately rejects all of the claims on appeal for failure to meet the requirements of the written description requirement and failure to meet the requirements of the enablement requirement (see the Answer, page 7). The written description and enablement requirements of § 112 are separate and distinct. *See Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). As recognized by the examiner (Answer, page 7), the written description requirement of § 112 requires that the applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed. *See Vas-Cath Inc.*, 935 at 1563, 19 USPQ2d at 1117. The initial burden of proof rests with the examiner in establishing that appellant has not met the written description requirement. *See In re Alton*, 76 F.3d 1168, 1175, 37 USPQ2d 1578, 1583 (Fed. Cir. 1996). However, we determine that the examiner has not met this burden merely

Appeal No. 2000-1747
Application No. 08/784,237

by criticizing the Example and Table in appellant's
specification (Answer, pages 4-7). The examiner has not
presented any convincing evidence or reasoning that the

Appeal No. 2000-1747
Application No. 08/784,237

written description does not convey with reasonable clarity to one skilled in the art that appellant was in possession of the invention as now claimed.

The initial burden of proof also rests with the examiner to support a rejection for lack of enabling disclosure. See *In re Wright*, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993). "Although not explicitly stated in section 112, to be enabling, the specification . . . must teach those skilled in the art how to make and use the full scope of the claimed invention 'without undue experimentation' [Citations omitted]." *Wright*, 999 F.2d at 1561, 27 USPQ2d at 1513. We determine that the examiner has not met this burden merely by showing that one example in appellant's specification contains "results of a somewhat schematic field test" which vary according to the user's perception (see the specification, page 5, lines 29-30; page 7, lines 10-16). We determine that the examiner has not explained why this example would have necessitated undue experimentation to practice the invention as now claimed.

Appeal No. 2000-1747
Application No. 08/784,237

For the foregoing reasons and those set forth in the Brief and Reply Brief, we determine that the examiner has not met the initial burden of proof required to support the rejections under

the written description and enablement requirements of 35 U.S.C. § 112, first paragraph. Accordingly, the examiner's rejections of claims 1 through 14 under 35 U.S.C. § 112, first paragraph, are reversed.

B. The Rejections under 35 U.S.C. § 102(b)

Under 35 U.S.C. § 102(b), a rejection for anticipation requires that the prior art reference disclose, either expressly or inherently, every limitation of the claims. See *In re King*, 801 F.2d 1324, 1326, 231 USPQ 136, 138 (Fed. Cir. 1986). All claim limitations must be considered, including the preamble of claims written in Jepson-type form. See *Rowe v. Dror*, 112 F.3d 473, 479, 42 USPQ2d 1550, 1553 (Fed. Cir. 1997) ("the claim preamble defines not only the context of the claimed invention, but also its scope"); and *Pentec, Inc. v. Graphic Controls Corp.*, 776 F.2d 309, 315, 227 USPQ 766, 770 (Fed. Cir. 1985) ("the claimed invention consists of the preamble in combination with the improvement"). Thus even though a Jepson-type claim results in an implied admission that the preamble is conventional or known, the claim must be considered as a whole.

The examiner finds that "Lambert discloses (3:3-31) dissolving amino acids, etc. into the solution that forms the hydrophilic layer" (Answer, page 8). Since appellant's specification discloses that amino acids are osmolality promoting agents, the examiner asserts that the claimed subject matter is anticipated by Lambert (*id.*, citing page 3, line 33 - page 4, line 2, of appellant's specification). However, the examiner's factual basis is incorrect since Lambert, at column 3, lines 3-31, discloses adding a catalyst for isocyanate curing which may be chosen from different types of amines (see column 3, lines 9-10 and 13-14). The exemplified amines taught by Lambert do not include any amino acids.² Accordingly, it is clear that the rejection of claims 1-3, 7-9, and 13-14 under 35 U.S.C. § 102(b) over Lambert cannot be sustained.

²The term "amino acid" is a known chemical term representing various amino-containing aliphatic acids such as glycine, leucine, etc. See *Hackh's Chemical Dictionary* 44-45 (3d ed., The Blakiston Co., New York, 1953, copy not attached). No acids, much less amino acids, are exemplified at column 3, lines 18-22, of Lambert.

The examiner finds that "Whitbourne discloses in examples 8, 17 and 18 mixing organic acid or inorganic acid into the PVP and in example 5(e) using urea formaldehyde resin" (Answer, page 9). The examiner does not identify where Whitbourne teaches "organic acid or inorganic acid" but considers the acetic acid of the aforementioned examples to be an osmolality promoting agent in view of appellant's disclosure that organic acids are useful as osmolality promoting agents (*id.*, citing page 3, line 24 - page 4, line 5, of appellant's specification). However, as correctly argued by appellant (Brief, page 14), appellant's specification first defines osmolality promoting agents and then lists classes of compounds which may include these agents (specification, page 3, lines 24-36). Appellant has challenged the examiner's finding that acetic acid is an osmolality promoting agent (Brief, page 14) and Whitbourne teaches that acetic acid is only used as a solvent for the hydrophilic polymer (see column 3, lines 8-10). On this record, the examiner has not met the burden of proof that the acetic acid exemplified by Whitbourne meets the claimed limitation of an "osmolality promoting agent." Accordingly,

Appeal No. 2000-1747
Application No. 08/784,237

the rejection of claims 1-3, 7-9, and 13-14 under 35 U.S.C. § 102(b) over Whitbourne cannot be sustained.

The examiner finds that Johansson teaches that an osmolality promoting agent may be mixed with a hydrophilic polymer (Answer, page 10, citing column 2, lines 15-24). In view of the examiner's claim interpretation that only the "improvement" need be shown, the examiner asserts that the claimed subject matter is anticipated by this disclosure of Johansson even though the reference discloses that the substrate already has a hydrophilic polymer coating before the osmolality promoting agent is applied (*id.*). However, in view of our claim construction as set forth above, all of the limitations of the claim must be considered, including the limitation that the method starts with a "substrate which was not previously provided with a hydrophilic coating" (see claim 1 on appeal; see also claim 7, where the medical device contains a single hydrophilic coating). With respect to separately argued claims 4-6 and 10-12 (Brief, page 17), we note that Johansson does not teach urea and that urea is not "a well known organic salt" (see the Answer, page 11, and *Hackh's Chemical Dictionary* 882 (3d ed., The Blakiston Co.,

Appeal No. 2000-1747
Application No. 08/784,237

New York, 1953, copy not attached)). For the foregoing reasons, the rejection of the claims on appeal under 35 U.S.C. § 102(b) over Johansson is reversed.

C. Summary

The rejection of claims 1-14 under 35 U.S.C. § 112, first paragraph, for failing to meet the written description requirement, is reversed. The rejection of claims 1-14 under 35 U.S.C. § 112, first paragraph, for failing to meet the enablement requirement, is reversed. The rejections of

Appeal No. 2000-1747
Application No. 08/784,237

claims 1-3, 7-9, and 13-14 under 35 U.S.C. § 102(b) as anticipated by Lambert or Whitbourne are reversed. The rejection of claims 1-14 under 35 U.S.C. § 102(b) as anticipated by Johansson is reversed.

The decision of the examiner is reversed.

REVERSED

TERRY J. OWENS)	
Administrative Patent Judge)	
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THOMAS A. WALTZ)	BOARD OF PATENT
Administrative Patent Judge)	APPEALS AND
)	INTERFERENCES
)	
)	
)	
ROMULO H. DELMENDO)	
Administrative Patent Judge)	

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Appeal No. 2000-1747
Application No. 08/784,237

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APPENDIX

1. In a method of forming a hydrophilic and osmolality promoting agent coating on the surface of a substrate which was not previously provided with a hydrophilic coating comprising applying, in one process step, a solution of agents which will combine to form the hydrophilic coating to the surface of the substrate and causing said agents to combine to form the hydrophilic coating, the improvement which comprises:

incorporating into said solution at least one osmolality promoting agent whereby the osmolality promoting agent is applied to the substrate in the same process step as said solution of agents.

7. In a medical device for introduction into a body cavity comprising a substrate having a surface and a single hydrophilic coating disposed on at least part of said surface and also having at least one osmolality promoting agent associated therewith, the improvement which comprises:

said osmolality promoting agent being incorporated in said hydrophilic coating itself.

Appeal No. 2000-1747
Application No. 08/784,237